

REMARKS

Reconsideration of this patent application is respectfully requested in view of the foregoing amendments, and the following remarks.

Reconsideration and withdrawal are respectfully requested for the rejection of the claims under 35 U.S.C. 102 and 35 U.S.C. 103 over *Berry U.S. Patent No. 5,098,376* and *Berry U.S. Patent No. 5,125,902*.

The amendments to this patent application are as follows.

Independent claim 30 has been amended such that the last paragraph recites the following subject matter:

"...wherein the oxygenator comprises a neighboring bundle of fibers, which is axially disposed in series along the longitudinal axis of the oxygenator, the bundles of fibers each having individual connection pairs, and both bundles of fibers being twisted in the same direction."

This claimed structure is clearly different from *Berry U.S. Patent No. 5,098,376*.

The original disclosure of this newly presented wording is mainly to be found in the characterizing portion of claim 30 as pending so far. It has been added that the neighboring bundle of fibers is "axially" disposed in series. This can be derived from the presence of the "longitudinal axis" in the pending main claim.

The "bundles of fibers having individual connection pairs" structure is derived from page 5 paragraph [0042] second last sentence of the publication document (US 2005/0232811 A1). There, it states:

"In the case of a plurality of fiber bundles accordingly having a plurality of connection pairs."

Finally, claim 30 now recites that "both bundles of fibers are twisted in the same direction," which is simply a shorter wording for "the second, neighboring bundle of fibers being twisted in the direction as the first bundle of fibers," which merely was the wording of pending claim 30.

The novelty and the nonobviousness over the citations are better emphasized with the amended wording of claim 30.

In the last Office Action, the Patent Examiner pointed out

that two random groupings of fibers in the system of *Berry '376* could be considered to be a first bundle and a second bundle.

This statement of the Patent Examiner is respectfully traversed, because the wording of claim 30 as pending so far demanded that the neighboring bundle of fibers be "disposed in series" (underlining added) with the first bundle of fibers. In contrast to this, a random grouping of fibers within the single fiber bundle of *Berry '376* would not be "in series." Instead, it would be arranged laterally in parallel.

In order to distinguish the claimed invention more precisely from *Berry '376*, claim 30 now recites the feature that the second bundle of fibers is "axially" disposed.

In addition to this, the amended claim 30 now recites that the two bundles of fibers each have individual connection pairs, i.e. individual pairs of "first connections" and "second connections."

This is also clearly distinguished from *Berry '376*, because in *Berry '376*, even if a random grouping of fibers came into existence, they would all have the same connections to the gas supply means respectively and to gas evacuation means.

In addition to being novel over *Berry et al '376*, the wording of amended claim 30 also describes an oxygenator which has a significant advantage over *Berry et al*.

Starting from a certain, given length of an oxygenator, the provision of at least two neighboring bundles of fibers along the axis of the oxygenator leads to a combination in which each of the fiber bundles comprises fibers, which are by far shorter than the fibers in *Berry et al '376*. In addition, the provision of "only" two fiber bundles reduces the average length of the fibers to half of the length of the fibers of *Berry et al '376*.

The effect of this reducing of the fiber length is described in detail in the U.S. Specification of the present patent application, see paragraph [0042] of the application publication *U.S. 2005/0232811 A1*:

"If the oxygenator has a plurality of fiber bundles arranged in series, it is proposed that they be all twisted in the same direction. The blood exerts a force onto the fibers spread into a layer, thus deforming the same. Depending on the turbulence and on the homogeneity of the flow, regions may form in which the fibers are for example too close so that the blood will find it difficult to flow through them. In view of this problem, it may be appropriate that the fibers have but the smallest possible length between two fixed fiber points, for example the connections. A constellation in which a plurality of fiber bundles are connected in series and twisted in the same direction has the advantage that the flow generated along the fibers over a long distance of the blood flow is particularly good without the various fibers becoming too unstable or so long that the gaseous mixture of oxygen and carbon dioxide flowing therein becomes too rich in carbon dioxide. In the case of a plurality of fiber

bundles accordingly having a plurality of connection pairs, oxygen supply may occur at each first connection. A stable structure consisting of a very large quantity of fibers may be provided, which advantageously implies a large overall fiber surface."

The present invention as recited in claim 30 cannot be rendered obvious by *Berry et al.* This is because *Berry et al.* explicitly provides one and only one elongated bundle of fibers. Moreover, *Berry et al.* did not recognize that it is of great advantage to have the fibers twisted in the operational state: *Berry et al* '376 discloses in column 5, line 60:

"Figure 2...perspective view of the embodiment...in which the gas permeable tubes are twisted elongated to form a small insertion diameter with respect to the outside diameter of the overall bundle of tubes" (underlining added).

This shows that *Berry et al* '376 only discloses a twisting of the fibers for the procedure of inserting the oxygenator into the human body through an opening of the human body which is as small as possible (see column 3, line 60: "apparatus...capable of being inserted with an over-the-guidewire insertion method").

There is no motivation in *Berry* to provide any elements making the oxygenator complicated by dividing the bundle of fibers into a plurality of bundles. Thus, it would not be necessary. Also, it would be contrary to the small oxygenator that *Berry et al* '376 clearly describes.

The present invention as recited in amended claim 30, in

contrast to *Berry et al '376*, provides several individual bundles of fibers. This is because the applicant has found out that the oxygenator provides much better results when the fibers are twisted in the operational state inside the human body. During the insertion procedure, also in contrast to *Berry et al '376*, the applicant keeps the oxygenator in a non-twisted state as shown in FIG. 1 of the present patent application.

The deficiencies in the teachings of the primary reference to *Berry et al '376* are not overcome by the teachings of the secondary reference to the *Berry U.S. Patent No. 5,125,902*.

Berry (902) in FIG. 6, and in column 12, in lines 42 to 49, teaches that prior to insertion of the blood gas exchange device 70 into the vena cavae as guided by the sheath 10, the overall diameter of the bundle of gas permeable tubes 72 is reduced by twisting and by further compression as best illustrated in FIG. 6. Although the compression shown in FIG. 6 is exaggerated, it does illustrate the compressing function of the receiving portion 22 of the sheath 10.

Thus, *Berry '902* teaches only a single bundle of fibers.

On Page 4 of the Office Action, the Patent Examiner has

stated that

"Applicant argues that Berry et al do not disclose a plurality of bundles. Examiner points out that the Applicant has not provided any limitations in the claims which would prevent any random grouping of adjacent fibers in the system of Berry from arbitrarily being considered a first bundle, and a second, adjacent group of fibers being considered a second bundle in which case both the fibers of the first and second bundles would be twisted in the same direction."

This is respectfully traversed, because of the amendment made to independent claim 30.

For all the reasons set forth above, none of the prior art references provide an identical disclosure of the claimed invention. Hence, the present invention is not anticipated under 35 U.S.C. 102, but is patentable under 35 U.S.C. 103, over all the prior art applied by the Patent Examiner. Withdrawal of these grounds of rejection is respectfully requested.

A prompt notification of allowability is respectfully requested.

Respectfully submitted,
GJORGIO CATTANEO ET AL.-2



COLLARD & ROE, P.C.

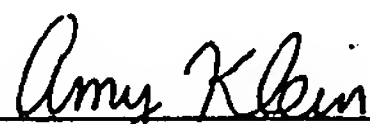
Edward R. Freedman, Reg. No. 26,048

1077 Northern Boulevard
Roslyn, New York 11576
(516) 365-9802

Attorney for Applicant

ERF:lgh

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on October 25, 2007.



Amy Klein